

Notice of Allowability

Application No.

09/551,494

Examiner

Ashwin Mehta

Applicant(s)

MEULEWAETER ET AL.

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to papers filed 30 June 2005 and the telephone interview of 27 September 2005.
2. ☒ The allowed claim(s) is/are 32,38-43 and 49-73.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>attached</u> . |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |

Claim Objections and Rejections

1. The objection to claim 42 is withdrawn in light of the claim amendment.
2. The rejection of claims 32, 38-43, 49-52, 54, and 58 under 35 U.S.C. 112, second paragraph is withdrawn in light of the claim amendments.
3. The rejection of claims 32, 38, 42, 43, 49, 54, and 58 under 35 U.S.C. 112, first paragraph is withdrawn in light of the claim amendments.

Examiner's Amendment

4. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Christopher North on September 27, 2005.

The application has been amended as follows:

In the claims:

Claim 32. A method for the introduction of inhibitory RNA in the cytoplasm of a plant cell, said inhibitory RNA reducing or abolishing the expression of a gene in the plant cell, said method comprising:

- a) introducing into said plant cell, a viral RNA vector derived from satellite tobacco mosaic virus, wherein said vector comprises said inhibitory RNA and an origin of assembly of

Art Unit: 1638

tobacco mosaic virus wherein said inhibitory RNA comprises a sense RNA or an antisense RNA, said sense or antisense RNA comprising a nucleotide sequence of at least 50 nucleotides having 95% to 100% sequence identity to the nucleotide sequence of [said] a target gene in said plant cell [or the complement thereof]; and

- b) introducing a corresponding helper virus into said plant cell.

Claim 38. The method of claim 32 [or 61], wherein said helper virus is tobacco mosaic virus.

Claim 39. A method for the introduction of inhibitory RNA into the cytoplasm of a plant cell, said inhibitory RNA reducing or abolishing the expression of a gene in the plant cell, said method comprising:

- a) introducing into said plant cell a viral RNA vector derived from satellite tobacco necrosis virus, wherein said vector comprises said inhibitory RNA and an origin of assembly of tobacco mosaic virus wherein said inhibitory RNA comprises a sense RNA or an antisense RNA, said sense or antisense RNA comprising a nucleotide sequence of at least 50 nucleotides having 95% to 100% sequence identity to the nucleotide sequence of [said] a target gene in said plant cell [or the complement thereof]; and
- b) introducing a corresponding helper virus into said plant cell, wherein said helper virus is derived from tobacco necrosis virus and comprises a coat protein gene of tobacco mosaic virus.

Claim 40. The method of claim 39 [or 61], wherein said satellite RNA virus is satellite tobacco necrosis vector strain 1 or 2 and said helper virus is derived from TNV-A.

Claim 41. The method of claim 39 [or 61], wherein said satellite RNA virus is STNV-C and said helper virus is derived from TNV-D.

Art Unit: 1638

Claim 42. The method of any one of claims 32, 38, 39 to 41, and 54[, 58, and 61], wherein said plant is selected from *Nicotinia* spp, *Oryza sativa*, *Zea Mays*, *Brassica* spp., *Gossypium* spp., *Triticum* spp., *Arabidopsis* spp. or *Petunia* spp.

Claim 43. A kit for the introduction of inhibitory RNA in the cytoplasm of a plant cell, said inhibitory RNA reducing or abolishing the expression of a gene in the plant cell, said kit comprising

- a) a viral RNA vector derived from satellite tobacco mosaic virus, wherein said vector comprises said inhibitory RNA and an origin of assembly of tobacco mosaic virus wherein said inhibitory RNA comprises a sense RNA or an antisense RNA, said sense or antisense RNA comprising a nucleotide sequence of at least 50 nucleotides having 95% to 100% sequence identity to the nucleotide sequence of [said] a target gene in said plant cell [or the complement thereof]; and
- b) a corresponding helper virus.

Claim 49. The kit of claim 43 [or 62], wherein said corresponding helper virus is tobacco mosaic virus.

Claim 50. A kit for the introduction of inhibitory RNA into the cytoplasm of a plant cell, said inhibitory RNA reducing or abolishing the expression of a gene in the plant cell, said kit comprising:

- a) a viral RNA vector derived from satellite tobacco necrosis virus, wherein said vector comprises said inhibitory RNA and an origin of assembly of tobacco mosaic virus wherein said inhibitory RNA comprises a sense RNA or an antisense RNA, said sense or antisense RNA comprising a nucleotide sequence of at least 50 nucleotides having 95% to 100% sequence identity to the nucleotide sequence of [said] a target gene in said plant cell [or the complement thereof]; and
- b) a corresponding helper virus derived from tobacco necrosis virus, said virus comprising the coat protein gene of tobacco mosaic virus.

Art Unit: 1638

Claim 51. The kit of claim 50 [or 62], wherein said satellite RNA virus is satellite tobacco necrosis vector strain 1 or 2 and said corresponding helper virus is derived from TNV-A.

Claim 52. The kit of claim 50 [or 62], wherein said satellite RNA virus is STNV-C and said corresponding helper virus is derived from TNV-D.

Claim 53. The method of claim 32, [wherein said viral RNA vector comprises] wherein said origin of assembly from tobacco mosaic virus has the nucleotide sequence of SEQ ID No 2 from the nucleotide at position 5443 to the nucleotide at position 5518.

Claim 54. The method of claim 32, [wherein said viral RNA vector comprises] wherein said origin of assembly from tobacco mosaic virus has the nucleotide sequence of SEQ ID No 5 from the nucleotide at position 5430 to the nucleotide at position 5505.

Claim 55. The method of claim 32, [wherein said viral RNA vector comprises] wherein said origin of assembly from tobacco mosaic virus has the nucleotide sequence of SEQ ID No 12.

Claim 56. The method of claim 32, wherein said viral RNA vector further comprises a STMV leader having the nucleotide sequence of SEQ ID No 4 from the nucleotide at position 1 to the nucleotide at position 197.

Claim 57. The kit of claim 43 [or 62, wherein said viral RNA vector comprises] wherein said origin of assembly from tobacco mosaic virus has the nucleotide sequence of SEQ ID No 2 from the nucleotide at position 5443 to the nucleotide at position 5518.

Claim 58. The kit of claim 43 [or 62, wherein said viral RNA vector comprises] wherein said origin of assembly from tobacco mosaic virus has the nucleotide sequence of SEQ ID No 5 from the nucleotide at position 5430 to the nucleotide at position 5505.

Claim 59. The kit of claim 43 [or 62, wherein said viral RNA vector comprises] wherein said origin of assembly from tobacco mosaic virus has the nucleotide sequence of SEQ ID No 12.

Claim 60. The kit of claim 43 [or 62], wherein said viral RNA vector further comprises a STMV leader having the nucleotide sequence of SEQ ID No 4 from the nucleotide at position 1 to the nucleotide at position 197.

Claim 61. The method of claim 32 or 39, wherein said sense RNA or said antisense RNA comprises a nucleotide sequence of at least 100 nucleotides having at least 95% to 100 % sequence identity of the nucleotide sequence of [said] a target gene in said plant cell [or the complement thereof].

Claim 62. The kit of claim 43 or 50, wherein said sense RNA or said antisense RNA comprises a nucleotide sequence of at least 100 nucleotides having at least 95% to 100 % sequence identity of the nucleotide sequence of [said] a target gene in said plant cell [or the complement thereof].

The following new claims were added:

Claim 63. The method of claim 32, wherein said sense RNA or said antisense RNA comprises a nucleotide sequence of at least 100 nucleotides having at least 95% to 100 % sequence identity of the nucleotide sequence of a target gene in said plant cell, and wherein said helper virus is tobacco mosaic virus.

Claim 64. The method of claim 39, wherein said sense RNA or said antisense RNA comprises a nucleotide sequence of at least 100 nucleotides having at least 95% to 100 % sequence identity of the nucleotide sequence of a target gene in said plant cell, and wherein said satellite RNA virus is satellite tobacco necrosis vector strain 1 or 2 and said helper virus is derived from TNV-A.

Claim 65. The method of claim 39, wherein said sense RNA or said antisense RNA comprises a nucleotide sequence of at least 100 nucleotides having at least 95% to 100 % sequence identity of the nucleotide sequence of a target gene in said plant cell, wherein said satellite RNA virus is STNV-C and said helper virus is derived from TNV-D.

Claim 66. The method of claim 61 wherein said plant is selected from *Nicotinia* spp, *Oryza sativa*, *Zea Mays*, *Brassica* spp., *Gossypium* spp., *Triticum* spp., *Arabidopsis* spp. or *Petunia* spp.

Claim 67. The kit of claim 43, wherein said sense RNA or said antisense RNA comprises a nucleotide sequence of at least 100 nucleotides having at least 95% to 100 % sequence identity of the nucleotide sequence of a target gene in said plant cell, and wherein said corresponding helper virus is tobacco mosaic virus.

Claim 68. The kit of claim 50, wherein said sense RNA or said antisense RNA comprises a nucleotide sequence of at least 100 nucleotides having at least 95% to 100 % sequence identity of the nucleotide sequence of a target gene in said plant cell, and wherein said satellite RNA virus is satellite tobacco necrosis vector strain 1 or 2 and said corresponding helper virus is derived from TNV-A.

Claim 69. The kit of claim 50, wherein said sense RNA or said antisense RNA comprises a nucleotide sequence of at least 100 nucleotides having at least 95% to 100 % sequence identity of the nucleotide sequence of a target gene in said plant cell, and wherein said satellite RNA virus is STNV-C and said corresponding helper virus is derived from TNV-D.

Claim 70. The kit of claim 62, wherein said origin of assembly from tobacco mosaic virus has the nucleotide sequence of SEQ ID No 2 from the nucleotide at position 5443 to the nucleotide at position 5518.

Claim 71. The kit of claim 62, wherein said origin of assembly from tobacco mosaic virus has the nucleotide sequence of SEQ ID No 5 from the nucleotide at position 5430 to the nucleotide at position 5505.

Claim 72. The kit of claim 62, wherein said origin of assembly from tobacco mosaic virus has the nucleotide sequence of SEQ ID No 12.

Claim 73. The kit of claim 43, wherein said sense RNA or said antisense RNA comprises a nucleotide sequence of at least 100 nucleotides having at least 95% to 100 % sequence identity of the nucleotide sequence of a target gene in said plant cell, and wherein said viral RNA vector further comprises a STMV leader having the nucleotide sequence of SEQ ID No 4 from the nucleotide at position 1 to the nucleotide at position 197.

5. Note that claims 53, 55, and 56 have been rejoined. These claims were previously withdrawn as a result of the restriction/election requirement mailed January 13, 2004, in which Applicants were required to select a nucleotide sequence for examination. Since these claims have been rejoined, that restriction requirement has been withdrawn. Applicants are advised that if claim(s) that include limitations of the instant claims are presented in a continuation or divisional application, such claims may be subject to statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

6. Claims 32, 38-43, and 49-73 are allowed.

7. The following is an examiner's statement of reasons for allowance: Applicants have developed a system for causing the post-transcriptional gene silencing of a gene in a plant cell,

Art Unit: 1638

comprising introducing into the cells a viral RNA vector derived from satellite tobacco mosaic virus or satellite tobacco necrosis virus, wherein the vector comprises an origin of assembly from tobacco mosaic virus and inhibitory RNA comprising RNA that is sense or antisense to a target gene and comprises a nucleotide sequence of at least 50 nucleotides having 95% to 100% identity to the nucleotide sequence of the target gene. A helper virus, encoding components such as a replicase, which are necessary in *trans* for replication of the viral RNA vector, is also introduced into the cell. Fitzmaurice et al. (WO 90/12107) teach a recombinant expression system based on satellite tobacco mosaic virus. However, the prior art does not teach or fairly suggest recombinant STMV or STNV vectors comprising an origin of assembly from tobacco mosaic virus.

Any comments considered necessary by Applicants must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Contact Information

Any inquiry concerning this or earlier communications from the Examiner should be directed to Ashwin Mehta, whose telephone number is 571-272-0803. The Examiner can normally be reached from 8:00 A.M to 5:30 P.M. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Jones, can be reached at 571-272-0745. The fax phone numbers for the organization where this application or proceeding is assigned are 571-273-8300. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the

Art Unit: 1638

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

September 27, 2005

A handwritten signature in black ink, appearing to read 'Ashwin D. Mehta', is positioned above the printed name.

Ashwin D. Mehta, Ph.D.
Primary Examiner
Art Unit 1638